REGULATORY GUIDE 4.6

GUIDE FOR THE PREPARATION OF OPERATING AND SAFETY PROCEDURES FOR ACCELERATORS, THERAPEUTIC RADIATION MACHINES, AND SIMULATORS

I. Introduction

Operating and safety procedures are required by 25 Texas Administrative Code (TAC) §289.229(f)(3)(B) for research and development and industrial accelerators and §289.229(h)(1)(D), (h)(2)(D)(iv), and (h)(3)(C)(v) for therapeutic radiation machines used in the healing arts and veterinary medicine. The model procedures in this regulatory guide are generalized. Procedures must be written that are specific for your facility. By using the sections of this guide that apply, a unique set of operating and safety procedures may be created. Although other formats are acceptable, information contained in §289.229(f)(3)(B) for research and development and industrial accelerators and §289.229(h)(1)(D), (h)(2)(D)(iv), and (h)(3)(C)(v) for therapeutic radiation machines must be included in your operating and safety procedures.

II. Sample Operating and Safety Procedures

OPERATING AND SAFETY PROCEDURES
FOR

_____
(name of facility)

A. General requirements for research and development, industrial accelerators, therapeutic radiation machines, and simulators.

This manual establishes procedures that will minimize radiation exposure to patients and employees. They are provided to comply with rules enforced by the Texas Department of Health, Bureau of Radiation Control (BRC). The rules require that each facility using accelerators and/or simulators be registered with the BRC.

The certificate of registration contains conditions and restrictions that apply to the operation of the radiation machines in this facility as well as a listing of the sections of the rules that apply. These rules are available for your review in/at (specify location) [See §289.203(b)]. The rules require that a Radiation Safety Officer (RSO) be designated. The RSO has the responsibility and authority for assuring safe radiation practices and serves as the contact person between this facility and the BRC. Direct all your questions or concerns on radiation safety to the RSO for this facility, (specify RSO name) [See §289.226(e)(2)].

1. Personnel Monitoring Requirements

   (a). Any adult who is likely to receive a dose from occupational exposure to radiation in excess of 500 millirem in a year must use an individual monitoring device such as a film badge or thermoluminescent dosimeter. Declared pregnant women who are likely to receive a dose from occupational exposure to radiation in excess of 50 millirem during the entire pregnancy must also use an individual monitoring device [See §289.231(n)].

   (b). The individual monitoring device shall be assigned to and must be worn only by one individual [See §289.231(q)(1)(A)].

   (c). Individual monitoring devices must be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar) [See §289.231(q)(1)(B)].

   (d). Additional individual monitoring devices used for monitoring the dose to the embryo/fetus of a declared pregnant woman must be located at the waist under any protective apron being worn by the woman [See §289.231(q)(1)(C)]. If multiple individual monitoring devices are worn by a declared pregnant woman, dose to the embryo/fetus and the occupational dose to the woman shall be determined in accordance with the rules [See §289.231(m)(1)(D)(iv)].

   (e). Individual monitoring devices that are not being worn and the control monitoring device will be stored in an area that is away from rooms where radiation machines are in use. This is in/at (specify location).

   (f). (specify name) is responsible for the occupational dose records and exchanging the individual monitoring devices on (specify exchange dates). The individual monitoring device readings (film badge reports) are located in/at (specify posting

or records location) .

(g). If you are working for another employer and receive an occupational dose, report that dose to the RSO so that it can be included in your annual record of occupational dose.

2. Posting notices, instructions, and reports to workers; and posting a radiation area.

(a). Read the "Notice to Employees" sign posted in/at (specify location) .

(b). The certificate of registration, operating and safety procedures, and any notices of violations involving radiological working conditions are located in/at (specify location(s)) [See §289.203(b)].

(c). Your rights and obligations as a radiation worker are found in §289.203(c),(d), and (e) of the rules.

(d). The room(s) in which the radiation machine(s) is/are located and operated is a radiation area and is restricted [See §289.231(x)].

3. Radiation incidents, overexposures, and therapy events (misadministrations).

The following incidents, overexposures, or misadministrations should immediately be reported to the RSO.

(i). stolen, lost, or missing radiation machines [See §289.231(gg)];

(ii). overexposures [See §289.231(hh)]; and

(iii). therapy events (misadministrations) [See §289.229(i) and (j)].

4. Training and credentialing for operators of equipment.

(a). Operators of accelerators used in research and development and industrial operations shall receive instruction in and demonstrate competence with the following [See §289.229(f)(4)]: This will be accomplished by (name method, i.e., classes, one-on-one-instruction by the RSO, reading and testing).

(I). operating and safety procedures;

(II). radiation warning and safety devices;

(III). identification of hazards associated with use of the equipment; and

(IV). procedures for reporting an actual or suspected overexposure.

A record shall be kept of this training [See Appendix A].

(b). Individuals who operate radiation machines for human use shall meet the appropriate credentialing requirements of rules issued in accordance with the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601. Copies of the credentialing document shall be maintained at each facility where the individual is working. They will be kept at (name location) [See §289.229(h)(1)(C)].

B. Requirements for accelerators used in research and development and industrial operations. [See §289.229(f)(3)(B)]:

1. The methods used to secure the accelerator from unauthorized use include (list methods specific to this facility and operation); and

2. The procedures for testing interlocks, entrance controls, and alarm systems include (list procedures specific to this facility to include):

(a). all interlocks shall be tested for proper operation on (date)(time)_____ by ____(name)_____.

(b). All visible or audible alarms shall be tested for proper operation on (date)(time) by __(name)_____.

C. Requirements for accelerators and simulators used only in the healing arts.

1. Ordering of radiation procedures and treatments. No radiation procedures or treatments shall be performed unless prescribed by a physician [See §289.229(b)(1)].

2. Operator/patient communication. The operator must be able to continuously view and communicate with the patient.

- therapeutic radiation machines operating below 1 MeV [See §289.229(h)(2)(B)]

- therapeutic radiation machines operating at or above 1MeV [See §289.229(h)(3)(B)(iv) and (v)]

- radiation therapy simulators [See §289.229(h)(4)(A)(iv)]

(a). Two-way verbal/aural communication between the patient and the operator at the control panel is established by means of (name method, i.e., intercoms, etc.) .

For treatment involving therapeutic radiation machines operating at or above 1 MeV, other methods of communication shall be used if excessive noise levels or treatment requirements make aural communication impractical. The alternative method is (name method) and has been submitted to and received approval from the Bureau of Radiation Control, Registration on (date) .

(b). (name system used, i.e., windows, mirrors, or closed-circuit television) shall be provided for continual observation of the patient. An alternate viewing system consisting of (name alternate, i.e., windows, mirrors, or closed-circuit television) shall be a backup in the event of failure of the primary system.

(c). If the viewing system and alternate system described in (b) are both inoperable, treatment shall not be performed until one of the systems is restored. Failure of the verbal/aural communication and/or viewing systems shall be reported to (RSO or alternate in his/her absence).

D. Calibrations and spot checks.

- therapeutic radiation machines operating below 1 MeV [See §289.229(h)(2)(D)(ii) and(iii)]

- therapeutic radiation machines operating at or above 1MeV [See §289.229(h)(3)(C)(ii) and (iii)]

- simulators [See §289.229(h)(4)(C)(vi)]

(1). Procedures for calibrations were developed by (name physicist) and shall be performed by (name physicist) .

(2). Spot checks were developed by (name physicist) and are to be performed by (name physicist) or by (name) with a review by a licensed medical physicist with a specialty in therapeutic radiological physics (name physicist) within five treatment days.

(3). The following are our procedures ____(include procedures)_____.

E. Additional requirements for simulators only.

1. Protective devices. Use protective devices, such as lead aprons, gloves, and shields, to reduce exposure to radiation and keep radiation exposure as low as reasonably achievable (ALARA).

(a). Protective devices must be used or provided in the following situations:

(i). when it is necessary for an individual other than the patient to remain in the room or hold a patient; and

(ii). when fluoroscopic procedures are being performed.

(b). Protective device(s) is/are stored in/at ___(specify location)___.

(c). Protective devices shall be checked annually for defects, such as holes, cracks, or tears. This check can be done by visually inspecting or feeling the protective devices or may also be done by x-raying these items. A record will be kept of this check [See Appendix B]. If a defect is found at the time of the annual check or on any other occasion, notify the RSO and remove the device from service until it can be repaired or replaced [See §289.229(h)(4)(A)(iii)].

2. Technique charts. Use of a technique chart aides in reducing the exposure to the operator and patient and it must be used for all exposures. Technique charts are displayed in the vicinity of the control panel of each x-ray machine and may be (choose one, two, or all of the following: written; electronically displayed; or graphically displayed) [See §289.229(h)(4)(A)(i)].

3. Film processing [See Appendix C].

(a). Unexposed film is stored __(describe location and procedures for storage)_____.

(b). Films shall be developed by the time and temperature recommended by the x-ray film manufacturer. These specifications are posted in/at ___(specify location)___ [See §289.229(h)(4)(A)(viii)(I)].

(i). Expiration dates on film and chemicals should be checked

periodically. New film or chemicals should be rotated so the oldest are used first. Do not use films or chemicals after the expiration date.

(ii). Safe light(s) in the film processing/loading area is/are provided under these conditions and should not be changed without authorization from the RSO [See §289.229(h)(4)(A)(viii)(IV)].

Filter type _____
Bulb wattage _____
Distance from work surfaces _____

(iii). If light leaks are seen around doors, ceilings, or other openings in the darkroom, notify the RSO.

(c). Alternative processing systems.

Users of daylight processing systems, laser processors, self-processing (Polaroid) film units, or other alternative processing systems shall develop procedures following manufacturer's recommendations for image/film processing [See §289.229(h)(4)(ix)]. These procedures are located at (location).

III. Acknowledgement.

Once you have reviewed these operating and safety procedures, sign and date the acknowledgement form [See Appendix D].

APPENDIX A

SAMPLE RECORD FOR DOCUMENTING TRAINING AND COMPETENCE IN RESEARCH AND DEVELOPMENT AND INDUSTRIAL OPERATIONS for

(name of facility)

The following individuals completed training in and demonstrated competence with the items in §289.229(f)(4).

Full Name_____Date _____

Full Name_____Date _____

Full Name_____Date _____

Full Name_____Date _____

Full Name_____Date _____

Full Name_____Date _____

Full Name_____Date _____

Full Name_____Date _____

Full Name_____Date _____

Signature of RSO_____Date_____

APPENDIX B

SAMPLE PROTECTIVE DEVICES SURVEY
(LEAD APRONS, GLOVES, THYROID SHIELDS, GONADAL SHIELDS)

ID#/LETTER (LIST TYPE of DEVICE)	OK	LIST DEFECTS	INITIAL & DATE
(Example: Apron #10)	OK		jd 2/2/02
(Example: Apron #11		Crack - mid section	jd 2/2/02

APPENDIX C

SAMPLE DARKROOM REQUIREMENTS LOG FOR CALENDER YEAR

Automatic processor (Model #, Serial #)

Developer temperature _____

Chemicals replaced (manufacturer's/chemical supplier's recommendations or every 3 months)

_____ _____

(initials) (date) (initials) (date)

_____ _____

(initials) (date) (initials) (date)

Darkroom light leak tests performed _____ _____

(every 6 months) (initials) (date) (initials) (date)

Lighting checked in film processing/loading area:

(every 6 months)

filter type _____

bulb wattage _____

distance from work surfaces _____

_____ _____

(initials) (date) (initials) (date)

Light leaks or related deficiencies noted _____

(initials) (date)

_____

(initials) (date)

Corrections of light leaks or related deficiencies (or attach service/work orders)

_____

(initials) (date)

_____

(initials) (date)

APPENDIX D

SAMPLE RECORD FOR INSTRUCTION OF INDIVIDUALS IN OPERATING AND SAFETY PROCEDURES FOR

(name of facility)

These procedures have been made available to each individual who operates the x-ray equipment on the date(s) indicated.

_____ _____

(Signature of RSO) (Date)

Equipment Operator Statement:

I have read these procedures and agree to abide by them.

_____

(Signature of Equipment Operator) (Date)

_____

(Signature of Equipment Operator) (Date)

_____

(Signature of Equipment Operator) (Date)

_____

(Signature of Equipment Operator) (Date)

_____

(Signature of Equipment Operator) (Date)